

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Application of:  
Michael E. Rickey, et al.

Application No.: Continuation of 10/278,011

Group Art Unit: Not Yet Assigned

Filed: July 25, 2003

Examiner: Not Yet Assigned

For: PREPARATION OF BIODEGRADABLE,  
BIOCOMPATIBLE MICROPARTICLES  
CONTAINING A BIOLOGICALLY ACTIVE  
AGENT

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**Information Disclosure Statement**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08a/b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO/SB/08a/b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
  - a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
  - b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure

Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

- c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).
3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
4. Relevance of the non-English language document(s) is discussed in the present specification.
5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.

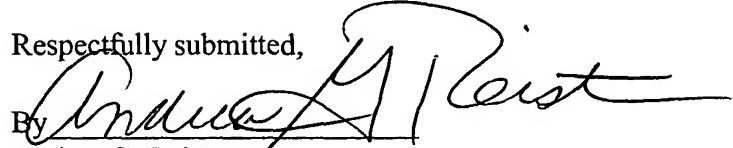
6. A concise explanation of the relevance of the non-English-language document(s) appears below:
7. The Examiner's attention is directed to co-pending U.S. Patent Application No. 10/278,011, filed October 23, 2002, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
8. Copies of the documents were cited by or submitted to the Office in Application No. 10/278,011, filed October 23, 2002, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a/b, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0740, referencing Docket No. 000166.00063-US09.

Dated: July 25, 2003

Respectfully submitted,

By   
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Substitute for form 1449/PTO				<b>Complete If Known</b>	
				Application Number	Continuation of 10/278,011
				Filing Date	July 25, 2003
				First Named Inventor	Michael E. Rickey
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	000166.0063-US09

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA		US-3,523,906-B1	08/1970	Vrancken	
AB		US-3,691,090	09/1972	Kitajima et al.	
AC		US-3,737,337	06-05-1973	Schnoring et al.	
AD		US-3,773,919	11/1973	Boswell et al.	
AE		US-3,891,570	06/1975	Fukushima et al.	
AF		US-3,960,757	06/1976	Morishita et al.	
AG		US-4,221,862	09/1980	Naito et al.	
AH		US-4,384,975	05/1983	Fong	
AI		US-4,389,330	06/1983	Tice et al.	
AJ		US-4,530,840	07/1985	Tice et al.	
AK		US-4,940,588-B1	07/1990	Sparks et al.	
AL		US-5,066,436-B1	11/1991	Komen et al.	
AM		US-5,407,609	04/1995	Tice et al.	
AN		US-5,478,564	12/1995	Wantier et al.	
AO		US-5,541,172-B1	07/1996	Labric et al.	
AP		US-5,650,173-B1	07/1997	Ramstack et al.	
AQ		US-5,654,008	08-05-1997	MEDISORB TECHNOLOGIES INTERNATIONAL, L.P.	
AR		US-5,688,801-B1	11/1997	Mesens et al.	
AS		US-5,792,477	08/1998	Alkermes Controlled Therapeutics Inc. II	
AT		US-5,916,598-B1	06/1999	Rickey et al.	
AU		US-5,945,126	08-31-1999	Thanoo et al.	
AV		US-6,110,503-B1	08/2000	Rickey et al.	
AW		US-6,290,983	09/2001	Rickey et al.	
AX		US-6,403,114-B1	03-07-2002	Rickey et al.	

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
BA		EP-0 486 959-A1	05/1992	Canal et al.	
BB		WO-WO 89/03678	05/1989	Lewis et al.	
BC		WO-WO 90/13361	11/1990	Tice et al.	
BD		WO-WO 94/10982	05/1994	Kino et al.	
BE		WO-WO 95/13799-A1	05-26-1995	Medisorb Technologies International L.P.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	Date Considered
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
				Application Number	Continuation of 10/278,011
				Filing Date	July 25, 2003
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				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	000166.0063-US09

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Baker, J.R., "Motionless Mixers Stir Up New Uses," Chemical Engineering Progress, 32-38 (June 1991).	
	CB	Beck, L.R. et al., Biology of Reproduction, 28:186-195 (February 1983).	
	CC	Bodmeier, R. et al., Pharmaceutical Research, 5:21-30 (1988).	
	CD	Conti, B. et al., "Use of polylactic acid for the preparation of microparticulate drug delivery systems," J. Microencapsulation, 9(2):153-166 (1992).	
	CE	Jalil, R. et al., Journal of Microencapsulation, 7(3): 297-319 (July-September 1990).	
	CF	Koch Engineering Co., Inc., Static Mixing Technology advertisement, pp. 1-15.	
	CG	Li, Wen-I et al., Journal of Controlled Release, 37: 199-214 (December 1995).	
	CH	Maa, Y.F. et al., "Liquid-liquid emulsification by static mixers for use in microencapsulation," J. Microencapsulation, 13(4):419-433, XP 000589904 (1996).	
	CI	Maulding, H.V. et al., Journal of Controlled Release, 3:103-117 (March 1986).	
	CJ	Mutsakis, M. et al., "Advances in Static Mixing Technology," Chemical Engineering Progress, 42-48 (July 1986).	
	CK	Sah, Hongkee et al., Pharmaceutical Research, 13:360-367 (March 1996).	
	CL	Sato, Toyomi et al., Pharmaceutical Research, 5:21-30 (1988).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	Date Considered
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